225-05-3000

Memorandum of Understanding Between the Food and Drug Administration and the Veterans Health Administration

I. Background

The Veterans Health Administration (VHA) and the Food and Drug Administration (FDA) share a critical reliance on high quality, up-to-date medication information and information systems. Terminology is an essential infrastructure for information systems, and as a result medication terminology is "mission critical" for both agencies. For example, FDA has invested in the development and ongoing maintenance of the drug listing database, and is planning an electronic labeling system. VHA computer systems use medication terminology to safety-check and fill drug orders nationwide (57 million outpatient prescriptions yearly).

The missions of the FDA and VHA intersect in the area of medication knowledge. FDA collects, verifies, and distributes medication knowledge that benefits patients, providers, researchers, the private sector, and others worldwide. VHA uses FDA-generated medication knowledge for patient care, research, and education. In turn, VHA creates medication knowledge through well-established research and academic programs.

High quality medical terminology and other medication information contained in package inserts, is a shared and critical need for FDA and VHA. Fortunately, collaboration can increase terminology quality and reduce its costs. The agencies have begun to develop a history of informal and formal collaboration on terminology and drug information projects via collaboration on the FDA's electronic labeling project and VA's National Drug File Reference Terminology (NDFRT) project.

II. Purpose

The purpose of this Memorandum of Understanding (MOU) is to extend an existing formal collaboration between FDA and VHA for the purpose of developing and implementing terminology standards for medication information.

III. Applicability

VHA and FDA will share information concerning terminology in medication information and will collaborate on projects related to this area including the electronic labeling information processing system, HL7 structured product labeling specification, and VHA NDFRT project.

IV. Scope of Work and Responsibilities

Based on common needs and a history of cooperation, this MOU establishes a formal mechanism for the Food and Drug Administration and VHA to collaborate on mutually beneficial terminology and drug information projects. Its scope includes collaboration in all

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areas of terminology and knowledge management, such as terminology development, evaluation, implementation, and maintenance. The agreement anticipates that a variety of resources could be shared within the limits of applicable laws and regulations to benefit agency stakeholders. Examples of resources that could be shared under this agreement include human, facility and financial assets, contracting vehicles, software, and data.

V. Amendment of Agreement

This agreement shall become effective on the date both parties have signed their approval below. Any amendments and modifications as may be necessary shall be developed jointly between representatives of each department. Such amendments and modifications shall become effective by the signature approval of the parties signatory to the agreement or by their respective official successors.

VI. Duration of Agreement

This agreement becomes effective upon the signature of both parties and will remain in effect until September 30, 2006, unless extended by mutual consent of both parties. Either party, upon 60 days notice in writing, may accomplish termination of this agreement.

VII. Disputes

Disputes concerning the interpretation of this agreement shall be resolved by majority vote of a three-person dispute resolution committee. The committee shall consist of one VA representative, one Food and Drug Administration representative and one neutral representative agreed upon by both VA and FDA.

VIII. Project Officers

For VHA:

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For FDA:

Randy Levin MD
Director for Health and Regulatory Data Standards
Food and Drug Administration
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IX. Acceptance By Both Parties To The Agreement

FOR THE DEPARTMENT OF VETERANS AFFAIRS, VHA

By (Signature) Robert M Kolodner

Name Robert M. Kolodner, M.D.

Title Acting VHA Chief Health Informatics Officer

Date 6/13/2005

FOR HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

By (Signature)

Name Janet Woodcock MD

Title Actg Deputy Commissioner for Operations

Date 6/28/05